No. 88-1434

(10)

IN THE
Supreme Court of the United States
OCTOBER TERM, 1988

ELIZABETH DOLE, Secretary of Labor, *et al.*,
Petitioners
v.
UNITED STEELWORKERS OF AMERICA, *et al.*

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF OF THE NATIONAL WHOLESALE DRUGGISTS' ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF AMICUS CURIAE

The National Wholesale Druggists' Association (NWDA) files this brief with the consent of the parties.

NWDA is an association of businesses engaged in the wholesale distribution of prescription and over-the-counter medicines and consumer products. Its membership includes drug wholesale companies operating drug distribution centers nationwide. Each distribution center has an average of 400 pharmacy customers, and distributes approximately 12,000 in-

dividual FDA-regulated drugs that appear to be subject to the Hazard Communication Standard (29 C.F.R. 1910.1200), implemented by the Occupational Safety & Health Administration (OSHA) of the Department of Labor.

NWDA's members are regulated under the OSHA standard through two particular provisions: 29 C.F.R. 1910.1200(b)(4), which discusses work operations where employees only handle chemicals in sealed containers which are not opened under normal conditions of use, and 29 C.F.R. 1910.1200(g)(7), which describes the duty of distributors to ensure that Material Safety Data Sheets (MSDSs) and updated information are provided to other distributors and employers. Even when only sealed containers are handled, MSDSs that are received by the wholesaler must be maintained and must be made accessible to employees under paragraph (b)(4)(ii) of the standard.

Products of particular concern to NWDA members are drugs regulated by the Food & Drug Administration (FDA) under the Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq.* The employers to whom these drugs are distributed are hospital, retail, and nursing home pharmacies.

Although not a party in the Third Circuit litigation below (855 F.2d 108 (3d Cir. 1988)), NWDA has participated extensively in the administrative and hearing stages of the OSHA rulemaking, as well as in the review of that rulemaking by the Office of Management & Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.* It was in part on the basis of NWDA's testimony at the public hearing of October 16, 1987, that OMB disapproved application of the OSHA standard to FDA-regulated drugs (Petition for Certiorari, p. 37a).

STATEMENT OF FACTS

FDA-regulated drugs are subject to substantial warning information requirements in the form of product labeling under the Food, Drug, and Cosmetic Act, *supra.* Data about new drug products are reviewed by FDA scientists, including pharmacologists and toxicologists, to assure that each drug is safe and effective for the indicated use with the patient and for the administering professional pharmacist, physician, and nurse.

FDA-required labeling under 21 U.S.C. 321 includes separate written sheets called "professional package inserts" (21 C.F.R. 1.3), one of which must be in each package. This information provides details of the product chemistry and its hazards. In addition, information from product labels and professional package inserts is compiled and published verbatim in commonly available texts as the *Physicians' Desk Reference* (42d Edition, 1988, Medical Economics Co., Inc., Oradell, NJ 07649), *Facts and Comparisons* (Looseleaf Drug Information Service, J.B. Lippincott Co., St. Louis, MO 63146-3098), and *USP Dispensing Information* (9th Ed., 1989, United States Pharmacopeial Convention. Inc., Rockville, MD 20852).

FDA-regulated drugs are exempt from OSHA *labeling* under 29 C.F.R. 1910.1200(b)(5)(ii). In addition, the standard as expanded to include non-manufacturers offers a *complete* general exemption for "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301,

et seq.), when it is in solid, final form for direct administration to the patient (i.e. tablets or pills)," 29 C.F.R. 1910.1200(b)(6)(viii). Due to the phrasing of this general exemption and its limitation to tablets and pills, the drug wholesaler remains obligated to maintain and to distribute MSDSs to pharmacies for FDA-regulated products in capsule, injection bottle, liquid, and other physical forms.

NWDA has estimated that *each* of its members' 310 distribution centers would have to retain 12,000 MSDSs and to pass on 4.8 million copies of those MSDSs (400 customers times 12,000 products). Based upon this burden, plus the present availability of detailed FDA-required chemical and hazard information in the form of professional package inserts and reference texts, and in light of the specialized knowledge of the professional employee audience, OMB disapproved the OSHA standard under the Paperwork Reduction Act as the standard applies to *all* FDA-regulated drugs. (OMB letter to Thomas Komarek, Oct. 28, 1987; Petition for Certiorari, Appendix E, p. 22a.) OMB found that "coverage of any FDA-regulated drug would result in duplicative paperwork and is unlikely to provide additional information of any practical utility." (*Id.*, p. 37a.)

SUMMARY OF ARGUMENT

The Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, is intended to minimize the Federal paperwork burden for individuals, small businesses and other persons. This statute vests the Director of OMB with certain specific review and approval functions with regard to recordkeeping, reporting, and paperwork required by federal agencies.

The OSHA hazard communication standard, as applied to FDA-regulated drugs, imposes an extremely burdensome and unnecessary paperwork redundancy through obligations upon FDA-drug wholesalers and pharmacists to obtain, distribute, retain, and update Material Safety Data Sheets for prescription medicines already covered by FDA paperwork requirements. Under OMB regulations, as well as the words of the Paperwork Reduction Act, burdens such as these are included in the information collection review process. OMB, in an appropriate hearing, found the general exemption for drugs offered in the OSHA standard to be inadequate because it was limited to pills and tablets and, therefore, OMB disapproved the standard as it would apply to any FDA-regulated drugs.

On Supreme Court review of the decision in *United Steelworkers, et al.* v. *Pendergrass, et al.*, 855 F.2d 108 (3d Cir. 1988), we ask the Court to find that the Third Circuit Court of Appeals erred—

(1) in concluding that the Paperwork Reduction Act is inapplicable to the paperwork burdens imposed by the OSHA standard;

(2) in ignoring the OMB regulations implementing the Paperwork Reduction Act, which explicitly declare this type of paperwork burden to be encompassed by the review process; and

(3) in misinterpreting the intent and effect of the OMB action as it pertains to FDA-regulated drugs.

ARGUMENT

I. BY THE TERMS OF THE PAPERWORK REDUCTION ACT AND THE OMB REGULATIONS IMPLEMENTING IT, THE OSHA STANDARD AS APPLIED TO FDA-REGULATED DRUGS WAS SUBJECT TO OMB REVIEW AND DISAPPROVAL.

The first purpose of the Paperwork Reduction Act, *supra*, is "to minimize the Federal paperwork burden for individuals, small businesses, State and local governments, and other persons." 44 U.S.C. 3501(1). An additional purpose expressed in the statute is "to coordinate, integrate and, to the extent practicable and appropriate, make uniform Federal information policies and practices." 44 U.S.C. 3501(4)*. One of the functions of the OMB Director is to "provide direction and oversee the review and approval of information collection requests" as well as "the reduction of the paperwork burden." 44 U.S.C. 3504(a). Section 3504(b), defining the Director's authority and functions, includes the responsibility to review government agencies' information collection proposals.

Section 3508 of the Paperwork Reduction Act states:

> Before approving a proposed information collection request, the Director shall determine whether the collection of information by an agency is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility. . . . To the extent, if any, that the Director determines that the collection of information by an agency is unnecessary, for any reason, the agency may not engage in the collection of the information.

* The interagency coordinating role for the OMB Director, defined in paragraph (4) of the purpose section of the Paperwork Reduction Act, is consistent with Section 4(b)(1) of the Occupational Safety & Health Act, 29 U.S.C. 653(b)(1), which declares that OSHA standards shall not apply "to working conditions of employees with respect to which other Federal agencies . . . exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."

The Paperwork Reduction Act defines "collection of information" to include "the soliciting of facts or opinions by an agency through the use of written report forms, application forms, schedules, questionnaires, reporting or recordkeeping requirements, or other similar methods. . . ." 44 U.S.C. 3502(4). The term "information collection request" is defined in subparagraph (11) of that section to mean "a written report form, application form, schedule, questionnaire, reporting or recordkeeping requirement, collection of information requirement, or other similar method calling for the collection of information." Subparagraph (17) defines "recordkeeping requirement" as "a requirement imposed by an agency on persons to maintain specified records."

Under the OSHA hazard communication standard, NWDA's members are obligated to maintain MSDSs that are received and to keep them accessible for inspection by employees and by OSHA compliance officers. All MSDSs that are received, in addition, must be duplicated and distributed to all pharmacist customers. This federal obligation is a reporting, recordkeeping, and collection of information requirement.

OMB's rules generally note that a proposed collection of information will not be approved "requiring respondents to maintain or provide information in a format other than that in which the information is customarily maintained." 5 C.F.R. 1320.6(j).

Chemical information about FDA-regulated drugs is customarily maintained in FDA-required labeling, including printed professional package inserts. It is *not* customarily maintained by the non-manufacturing wholesaler or pharmacy on MSDS forms. Examples of such package inserts as well as the detailed FDA-required information reproduced in texts such as the *Physicians' Desk Reference, Facts and Comparisons,* and *USP Dispensing Information, supra,* were included in Appendices to the NWDA Testimony Before the Federal Office of Management & Budget, October 16, 1987, which is part of the OMB administrative record. The insert goes into or is affixed to each package, and wholesalers, pharmacists and other people who use this information regularly maintain copies of the bound texts. Through this existing FDA system, effective hazard communication involving labeling, paperwork and training is in place. The information found on a typical MSDS is much less specific, and less effective as a communication to a pharmacist whose training is based upon the style of FDA labeling and professional package insert information. The data in a professional package insert differs somewhat in format from an OSHA MSDS, but it conveys essentially the same information. This different format carries the benefit of being more familiar to the specific audience for which it has been prepared—the same audience of distribution, pharmacy and medical employees as that targeted by the OSHA hazard communication standard.

Section 3516 of 44 U.S.C. mandates that the OMB Director "promulgate rules, regulations, or procedures necessary to exercise the authority provided by this chapter." Section 1320.7(c) of OMB's regulations defines the "collection of information" as the obtaining or soliciting of information, and goes on to define

such solicitation as including "any requirement or request for persons to obtain, maintain, retain, report, or publicly disclose information." Subparagraph (c)(2) says:

> Requirements by an agency or a person to obtain or compile information for the purpose of disclosure to members of the public or to the public at large, through posting, notification, labeling, or similar disclosure requirements, constitute the "collection of information" whenever the same requirement to obtain or compile information would be a "collection of information" if the information were directly provided to the agency. . . .

This definition section also states explicitly that " '[r]ecordkeeping requirement' . . . includes requirements that information be maintained or retained by persons *but not necessarily provided to an agency*" (5 C.F.R. 1320.7(r)), and that " '[r]eporting requirement' means a requirement imposed by an agency on persons *to provide information to another person* or to the agency" (5 C.F.R. 1320.7(s)) (Emphasis supplied.)

Typical MSDSs fill several pages. Using NWDA's estimates drawn from its own membership, each distribution center services an average of 400 customers with a universe of 12,000 affected products that would require MSDSs. (Approximately 4,000 drug wholesalers operate in the U.S., not all of whom are represented by NWDA, but all of whom are facing this crisis.) If each MSDS were 4 pages long, each NWDA member's distribution center would have to duplicate and distribute an average of 19.2 million sheets of paper to customers who already have virtually the same information in a different format in their *Physicians' Desk Reference, Facts*

and Comparisons, or *USP Dispensing Information*, *supra*.

This is exactly the type of duplicative and useless burden the Paperwork Reduction Act was designed to curtail. That MSDSs for each product need not be filed directly with OSHA is irrelevant—they are required of all employers by a government agency in a specific format with specific entries as records to be obtained, retained, distributed and updated. This paperwork also must be available for inspection by employees and government compliance officers. The Congressional concern addressed by the Paperwork Reduction Act was the burden on the people who are required to complete federal paperwork. The identity or address of the recipient in no way lessens the burden suffered by any business needlessly compelled to copy and distribute millions of sheets of paper that substantially repeat what is already on every recipient's shelf.

II. THE THIRD CIRCUIT'S REFUSAL TO ACKNOWLEDGE THE OMB REGULATIONS IS REVERSIBLE ERROR.

The OMB regulations in 5 C.F.R. Part 1320 implementing the Paperwork Reduction Act unquestionably describe the paperwork burden imposed upon NWDA's members and others by the expanded OSHA standard. However, in holding that the OSHA standard does not involve "collection of information" under the Paperwork Reduction Act, the Third Circuit did not even acknowledge the existence of these rules despite the fact that the rules were discussed extensively in the government's brief to that court.

This is inexplicable. It is well established that "the construction of a statute by those charged with its execution should be followed unless there are compelling indications that it is wrong. . . ." *E.I. duPont*

de Nemours & Co. v. *Collins*, 432 U.S. 46, 54-55 (1977) (quoting *Red Lion Broadcasting Co.* v. *FCC*, 395 U.S. 367, 381 (1969). This Court has stated:

> "We have often noted that the interpretation of an agency charged with the administration of a statute is entitled to substantial deference." *Blum* v. *Bacon*, 457 U.S. 132, 141 (1982). "To uphold [the agency's interpretation] 'we need not find that [its] construction is the only reasonable one, or even that it is the result we would have reached had the question arisen in the first instance in judicial proceedings.' . . . We need only conclude that it is a reasonable interpretation of the relevant provisions." *American Paper Institute, Inc.* v. *American Electric Service Corp.*, 461 U.S. 402, 422-423 (1983), quoting *Unemployment Compensation Comm'n* v. *Aragan*, 329 U.S. 143, 153 (1946).

Aluminum Co. v. *Central Lincoln People's Utility District*, 467 U.S. 386, 389 (1984). *Accord*, *Udall* v. *Tallman*, 380 U.S. 1, 16 (1965) (deference is particularly due to an administrative interpretation involving "a contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion").

Moreover, the deference owed the agency's interpretation takes on particular significance when that interpretation is embodied in legislative-type regulations promulgated pursuant to a grant of authority such as that found in 44 U.S.C. 3516. Agency legislative regulations implementing its enabling legislation have the force and effect of law and are entitled to great weight. Unless the regulation embodies a construction of the statute "contrary to clear congressional intent," a court "may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of

an agency." *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984). *See also, United States* v. *Morton*, 467 U.S. 822, 834 (1984) ("[b]ecause Congress explicitly delegated authority to construe the statute by regulation, in this case we must give the regulators legislative and hence controlling weight unless they are arbitrary, capricious or plainly controry to the statute"); *accord, Batterton* v. *Francis*, 432 U.S. 416, 424-426 (1977).

Here, the OMB regulations are plainly consistent with Congress' intent. The Senate Report on the Paperwork Reduction Act expressly states that the definition of "recordkeeping requirement" as found in that Act "includes information maintained by persons which may be but is not necessarily provided to a Federal agency." S. Rep. No. 96-930, 96th Cong., 2d Sess. 40, *Reprinted in* 1980 U.S. Code Cong. & Admin. News 6241, 6280. Moreover, in considering amendments to the Act in 1984, Congress was aware of OMB's construction of the Act found in its regulations, and took no steps to alter that construction. *See*, S. Rep. No. 98-576, 98th Cong., 2d Sess. (1984). "[C]ongressional failure to revise or repeal [an] agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." *Young* v. *Community Nutrition Institute*, 476 U.S. 974, 983 (1986), *quoting NLRB* v. *Bell Aerospace, Inc.*, 416 U.S. 267, 275 (1974). *Accord, Red Lion Broadcasting, supra*, 395 U.S. at 381-382.

Thus, the Third Circuit committed manifest error in refusing to acknowledge, much less discuss and analyze, OMB's regulations implementing the Paperwork Reduction Act that are clearly on point.

III. THE THIRD CIRCUIT OPINION ERRONEOUSLY CONFUSED THE EFFECT AND IMPORT OF THE OMB ACTION WITH REGARD TO OSHA'S GENERAL EXEMPTION OF FDA-REGULATED DRUGS.

It is important to note the Court of Appeals' apparent misunderstanding of the action taken by OMB with regard to FDA-regulated drugs. Although a *labeling* exemption has existed and was continued in the OSHA standard for consumer products and FDA-regulated drugs, a new *general* exemption was created, but only for a limited number of consumer products and FDA-regulated pills and tablets. OMB's disapproval did not criticize the new general exemptions because they were unwarranted, as the Third Circuit implies, but because they did not go far enough. OMB found that MSDS requirements on FDA-regulated drugs are grossly burdensome for distributors and pharmacists, duplicative of existing paperwork, and of little utility to anyone. The Third Circuit, however, appears to have confused the labeling and general types of exemption, and seriously misstated the OMB position:

> Whatever else the terms "collection of information" or "information collection requests" may refer to, they cannot possibly refer to these exemptions from labeling requirements imposed in the interest of health and safety by other federal regulatory agencies.

55 F.2d 108, 112.

As a result of the confusion, the court passed over the FDA issue and devoted the bulk of its opinion only to the substantially different multi-employer worksite issue. The court closed its opinion by declaring the general exemptions to be a "logical outgrowth" of the original administrative record, but

again appeared to misconstrue OMB's disapproval as destroying those exemptions rather than being a finding of insufficient breadth. OMB declared the standard unenforceable with regard to *all* FDA-regulated drugs. The standard may have been expanded pursuant to court order but, as noted in 5 C.F.R. 1320.4(c)(1), the Director "will independently assess any collection of information to the extent that the agency exercises discretion in its implementation." The creation of general exemptions was a "logical outgrowth" of the record within OSHA's discretion and was appropriate for OMB review.

CONCLUSION

For the foregoing reasons, the Third Circuit decision with regard to the OMB disapproval under the Paperwork Reduction Act of any OSHA coverage of FDA-regulated drugs should be reversed.

Respectfully submitted,

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